HIT Standards Committee
Summary of the April 28, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 12th meeting of the HIT Standards Committee (HITSC). She reminded the participants that this was a Federal Advisory Committee with an opportunity for the public to make comment, and conducted roll call.

2. Opening Remarks From the National Coordinator

David Blumenthal, National Coordinator for Health Information Technology, reported that ONC staff are working hard to respond to the many comments from the public and from this group about the Interim Final Rule (IFR) on standards and certification criteria, and on the certification process. It is hoped that those final rules will be released this spring. Based on HITSC's work to date, Congress has added additional responsibilities for the group through the recent health reform legislation. Section 1561 of the law, entitled *Health Information Technology Enrollment Standards and Protocols,* directs ONC and the HITSC to work in a slightly different but important direction to promote the realization of health reform.

Concurrent with these activities, the ONC is thinking further about the governance of the Nationwide Health Information Network (NHIN), which is part of the Health Information Technology for Economic and Clinical Health (HITECH) legislation and continuing to work much more intensively on the implementation of its grant programs. ONC also is preparing to work with the physician, hospital, nursing and clinician communities once meaningful use is finally defined.

3. Overview of the Meeting

Jonathan Perlin, HITSC Chair, discussed the evolving nature of the Committee's efforts, which have shifted to include consideration of the fact that implementation is beginning to occur on a practical level. To that end, a presentation by Doug Fridsma was added to the meeting's agenda to help guide the conversation about orienting the Committee towards its next set of activities.

HITSC Vice Chair John Halamka explained that the work ahead involves taking the 2013 and 2015 necessary transactions, breaking them out into domains, and determining how best to address them (within the context of both meaningful use and health care reform). There is a set of administrative transactions that have both policy and technology implications—the group must identify how to organize itself to deal with the work that falls outside of meaningful use. This may require the formation of joint workgroups between the HITSC and HIT Policy Committee (HITPC).

Jonathan Perlin offered an amendment to the minutes from the last HITSC meeting, held on March 24, 2010: on page 7, the reference to "*government* of standards-development organizations…"

should read as "*governance* of standards development organizations..." Otherwise, the minutes were approved by consensus.

> **Action Item #1:** Minutes from the last HITSC meeting, held on March 24, 2010, were approved by consensus with one correction: on page 7, the reference to "*government* of standards-development organizations…" should read as "*governance* of standards development organizations..."

4. Implementation Workgroup

Cris Ross explained that the Implementation Workgroup has been focused on work that began with trying to understand what plays into "success" from those who had implemented innovation both within and outside of health care. The Workgroup tried to identify success stories from vendors and their partners; from this work, the group concluded that a series of implementation toolkits is needed. For example, how can resources be made available so that a small physician practice that is not connected to a sophisticated provider can find the necessary tools to get started? How can a space be created in which resources are available in a noncommercial way to begin implementation efforts?

The Implementation Workgroup hopes to piggyback on one of a series of Requests for Proposals (RFPs) that have been issued by ONC. This particular RFP is entitled *Standards and Interoperability Framework: Interoperability Tools and Standards Repository*. The Implementation Workgroup's goals fit naturally with what this RFP calls for (i.e., to provide some structured places for resources to be made available to the public to begin implementation). This RFP has not yet been awarded; the Workgroup hopes that ONC staff will work closely with Workgroup members to assist that coordination, so that some of their objectives can be built into the award once the work associated with the RFP begins.

Liz Johnson noted that very recently, a $19 million communications grant was awarded. As part of this grant, 2-page success stories for will be collected and prepared for publication (although the specific workflow for this activity has not yet been determined).

The discussion that followed included these points:

- John Halamka noted that Doug Fridsma has provided a list of all the RFPs that fit into the ONC standards and interoperability framework. The list appears on John Halamka's blog.

- Noting the heterogeneity of the health care environment, Carol Diamond asked whether the distribution of distribution of implementation efforts has been considered. There is a plurality of certifiers now—those certification entities could specialize in certain areas. For example, certain certifiers might be more geared toward primary care and thus they would be collecting information about implementation in that arena. Cris Ross suggested that this would be an appropriate agenda item for the Implementation Workgroup's next meeting (i.e., how to segment that and what to focus on).

- Chris Chute asked to what degree a federated model of required infrastructure can be identified that would enable these kinds of implementation visions. For example, he said, it appears obvious that having a national repository of value sets is going to be helpful for many users, whether they be independent physicians working through a mediator, large organizations, or vendors. This is an example of a critical component infrastructure. Chris Chute asked how the Workgroup should go about identifying which of these components are critical paths, which might be best managed in a quasi-centralized fashion, and which can exist in a true, distributed model.

- Jim Walker advocated the employment of user-centered design and setting aside some resources for measuring which components work for which audiences. This practice rarely occurs with toolkits as they are developed, and toolkit developers often are dismayed at the usage patterns of their kits.

- Wes Rishel noted that a number of initiatives relating to the Health Insurance Portability and Accountability Act (HIPAA) are directed through the National Committee on Vital and Health Statistics (NCVHS.) He asked if there was any coordination plan between these two initiatives and the Implementation Workgroup. David Blumenthal explained that the ONC is required to coordinate with NCVHS or at the very least maintain communication so that both sides are informed. The NCVHS has traditionally led in providing advice on matters related to the administrative standards part of HIPAA. There is a requirement that the HITSC and HITPC move beyond administrative simplification to examine the simplification of enrollment, both within and outside the health care arena.

5. New Direction of HIT Work

Doug Fridsma presented a slide to illustrate the standards and interoperability framework that corresponds to many of the RFPs that have been issued. He asked Committee members to consider what type of mechanism could be employed to coordinate this work, not only with regard to meaningful use, but also related to administrative transactions and health care reform. The RFPs provide examples of initiatives that could be funded, but do not specifically indicate that they should be built as part of this coordination effort. The goal is to create a mechanism that would allow funding of those priorities. There is also flexibility in the detailed technical letter that allows, within the scope of the RFP, for the creation of a direction or a focus and would essentially redirect some of the resources in a way that would continue to support the mission, if the mission changes.

The Committee's discussion included these points:

- Cris Ross clarified that the Implementation Workgroup knows that there is no way that an advisory committee engaged in "do-it-yourself" projects could meet the extensive needs of the community.

- David Blumenthal explained that the new responsibility of the ONC is to develop a nationwide, interoperable, private, and secure electronic health information system. The Office is not in the passive mode of waiting for all of the pertinent parties to come together spontaneously; it has a

mandate to lead this. At a minimum, ONC's responsibility is to develop the standards, implementation specifications, and certification criteria, which, if the political will exists, would support interoperability, and to do so as fast as possible. This points to the need for the HITSC and HITPC to make sure that the National Coordinator knows exactly where there are adequate standards and specifications, and where they are lacking. In the areas where they are lacking, the Committees need to point the ONC in the direction that will enable their development.

- Carol Diamond discussed the belief that architecture is policy. Architecture makes determinations about where information is, how it is shared, who has access to it, etc. She suggested that the HITSC Workgroups have reached a level of maturity such that it is time to coordinate frameworks and ensure that, as the NHIN Direct work and the policy work proceed, these efforts have the answers that they need. She advocates creating a holistic framework to address these issues.

- Wes Rishel noted that there is an opportunity in that the stimulus bill created an artificial economic incentive for interoperability. If that interoperability can be achieved by the end of this artificial incentive, there is a good chance it will continue. Once organizations have made the investment, resolved the issues related to data sharing, and worked through the other challenges, it is easier for them to keep going. The Committee should keep in mind that it is working in an environment in which no standard is ever complete. He urged Committee members to continue looking for incremental areas in which to make progress, and to make it possible for those who want to make use of this artificial incentive to do so.

- Kevin Hutchinson noted that much has changed since this Committee was established early last year. He suggested taking a step back to examine how the HITSC is structured within its Workgroups and consider whether this structure accounts for the environmental changes that have occurred since the HITSC began.

- John Halamka noted that per the health care reform legislation, the HITPC and HITSC have 149 days left to develop interoperable and secure standards for protocols to facilitate enrollment of individuals. Issues include: (1) patient identity matching, (2) providing electronic documentation and digitization for verification of eligibility, (3) the reuse of eligibility, (4) patient engagement for being involved in the eligibility process, (5) content and security. A new plan may be needed to accomplish these tasks within the given timeframe.

- David Blumenthal noted that Congress and the Administration are trying to increase the number of people who have insurance, and they want to make it easy for people to get insurance. This noble aspiration has been part of President Obama's health care vision from the time he announced his own health plan in May 2007. However, it does mean that the various systems that support the different social services have to be interoperable in some way. It is that interoperability that is sought through Section 1561, and Congress turned to the HITPC and HITSC for guidance on this task.

- The ONC is beginning a dialog within the Department of Health and Human Services, and hopefully shortly across other agencies (e.g., Department of Agriculture, Department of

Housing and Urban Development, Internal Revenue Service, Treasury Department, etc.). These organizations have regular electronic contact with people who are uninsured and are potentially eligible for substantial federal subsidies or expanded federal programs starting in 2014.

- Interoperability poses a significant challenge; David Blumenthal commented that the HITSC and HITPC may not have all of the necessary perspectives represented. The Committees are examining the possibility of establishing workgroups that combine Committee members' expertise with that of outside experts.

- John Derr emphasized that long-term, post-acute care must be included in the discussion if interoperability in the entire spectrum of care is to be achieved.

> **Action Item #2:** Committee members agreed by consensus to provide additional input to David Blumenthal, Doug Fridsma, and the ONC on: (1) the activities and spectrum of interoperability framework and recommendations on cross-links necessary for the appropriate structure to support, (2) the recommendations that arose in terms of the pragmatism and representation, and (3) linkages between the HIT Policy and HIT Standards Committees.

6. Privacy and Security Workgroup Update: Consent Standards

Privacy and Security Workgroup Chair Dixie Baker explained that up to this point, the group has focused primarily on security standards, and to some degree privacy standards. For the most part, the Stage 1 meaningful use requirements did not have a great amount of consumer engagement content—there is an increasing amount of this content in Stages 2 and 3. In addition to offering an update in the area of standardization, privacy, and security, Dixie Baker also explored with the Committee some of the needs for standards that are upcoming in Stages 2 and 3 as well as in the consumer engagement aspects of Section 1561.

The Privacy and Security Workgroup examined the privacy management reference model that was initially developed by the International Security Trust and Privacy Alliance and adopted by OASIS. This is a framework for resolving privacy policy that identifies the services that would be needed to manage end-to-end privacy consent. The Workgroup has also examined the Integrating the Healthcare Enterprise (IHE) profile called Basic Patient Privacy Consent (B2PC). This is a very simple and direct profile for capturing the fact that a patient is aware of and has signed a consent, regardless of what it is (it is a CDA document exchange).

Next, Workgroup members will examine HL7 efforts both in its domain analysis model as well as its composite privacy consent directive, which is the intended replacement of B2PC. The HITPC's Privacy and Security Policy Workgroup is also engaged in this activity.

Dixie Baker then discussed engaging patients and families, illustrating the combination of the objectives that were identified by the HITPC and those objectives that were adopted in the Notice of Proposed Rulemaking (NPRM) that was issued on meaningful use. The goal is to provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health. The objectives for 2013 and 2015 are for consumers to become

increasingly engaged in their own care. For 2013, the objectives developed by the HITPC were to provide consumers with a personal health record (PHR) that is populated in real time, secure patient-provider messaging, secure e-mail, educational resources, patient preferences, and the ability to incorporate data from home monitoring devices. In essence, there is a general trend for more and more care to migrate out of hospitals and into homes. In 2015, the objectives are in the area of incorporating more decision support for consumers, self-management tools, and the ability to electronically report on their experience of care. Dixie Baker commented that within these meaningful use measures that are anticipated for 2013 and 2015, it is clear that there are not adequate standards.

Steve Findlay noted that the Workgroup is borrowing a concept called "nudging," which was made popular a few years ago in the book, *Nudge: Improving Decisions about Health, Wealth, and Happiness* by Cass Sunstein and Richard Thaler. He described "nudging" as nothing more than the art of guiding consumer behavior by manipulating the ecosystem of choice and decision-making.

Dixie Baker discussed consumer permissions (e.g., consent to send health information to a payer, authorization to disclose psychotherapy notes, etc.), explaining that as consumer engagement increases, a number of new permissions arise, such as the permission to exchange secure e-mail with one physician, and permission to query a home medical device. There is also the permission for a PHR vendor to query the home device, and then the permission to use that health information to direct self-management tools. PHR vendors are looking to provide these self-management tools and push providers towards certain products and procedures, etc. Doing so requires some level of data mining and examining the data to determine what tools to make available to the patients. All of these are new permissions that have not yet been thought through.

The following points were raised during the discussion:

- David McCallie asked where this data is being aggregated and under whose control it is. He noted that discussion has used the terms "HIE" and "PHR" as if they are well-defined entities. He further suggested that they are not, and that there is a cross between those two entities that he termed "health record bank." As the Committee starts to wrestle with the convergence of policy issues around consent and control, it must continue to consider the question of where this data is landing and whose control is it under in the first place. What will it take to have that data land in a place that both serves the consumer's needs to take control of it if they wish, and also the needs of the providers who need to know that this is secure and integral data?

- John Halamka noted that the ONC has published a white paper that examines a framework for consent. It is not trying to solve the problem, but it identifies the types of consent in use in this country: opt in, opt out, opt in and out with restrictions, etc. When there is a policy framework that can constrain the standards that are used, it would be helpful to have a finite number of consent possibilities for which standards have been selected.

- Jim Walker encapsulated the questions that need to be answered. What standards are in fact needed, and in what order? How simple can the standards be for them to get started? How can the Committee have a rational plan for making those standards more and more subtle, as the use cases develop?

- David McCallie suggested that anyone who has not established an account with a social networking site and looked through the site's privacy standards ought to do so to understand

the complexity of choices that are available for data that is arguably less sensitive than health data. Facebook is also an illustration of how it is possible to develop a consumer-friendly user interface that provides a large amount of control over sensitive data. The downside is that Facebook is a proprietary vendor, and it can change the rules at any time. There is a balance, particularly around health data, that does not look like the complete, sole-source control model of Facebook.

- David McCallie referenced a presentation by Bill Stead from Vanderbilt in which he argued that in terms of documenting clinical encounters, the raw data of the encounter should be preserved. Tools to extract the summary information that is necessary based on today's knowledge could then be applied, while preserving the raw data so it would be available in the future to be used in other ways that have not yet been discovered.

7. Clinical Quality Workgroup Update

Clinical Quality Workgroup Chair Janet Corrigan reported that the Workgroup is waiting to hear from the HITPC about what would be best in terms of 2013 and 2015 meaningful use measures. In the meantime, the Workgroup is gathering information about what is potentially feasible in terms of 2013 measures. One option is to identify e-measures that are currently in use in health care settings: those that are being used for quality improvement and public reporting purposes, in health care settings that have had EHRs and PHRs for a number of years (i.e., so that they are advanced in terms of their use).

The Workgroup is proposing to carry out an environmental scan of a limited number of these organizations, asking them to identify e-measures for which: (1) HIT tools play a particularly important role in facilitating rapid improvement (e.g., what are some of those areas where getting and properly using an EHR will make a real difference in the care provided?); and (2) HIT alone is not adequate to facilitate improvement, but rather, will require significant workflow or care process or redesign, or significant behavioral change on the part of the patient.

The Workgroup will start with the organizations that are represented around the HITSC table, by sending a request for some initial information. They will then post the results for public comment, in an effort to involve input from outside the Committee. The results will be shared with the HITSC and HITPC, and this will help to increase the pool of candidate measures to choose from once HITPC's priorities for 2013 come forward. It may also stimulate HITPC's thinking in terms of the particular areas that they identify as the best ones for 2013 and 2015.

Floyd Eisenberg updated the Committee on retooling efforts. One hundred and ten existing measures are being retooled into an electronic format. For that process, a prototype-authoring environment has been created; 42 measures have now been retooled from three measure developers. They have delivered the preliminary format to the Centers for Medicare and Medicaid Services (CMS), and in discussions on some format changes. They will subsequently be placed into the HL7 standard, e-measure representation of the Health Quality Measures Format (HQMF), which provides a more human-readable form than the current spreadsheet output.

The Committee brought up the following points in their discussion:

- Carol Diamond cautioned that it is helpful to look at measures that already exist, but the Committee and the Workgroup are facing a unique opportunity to examine important goals with regard to health improvement, outcomes, and interoperability. If measures for those

do not exist, perhaps the process should be flipped and some of these organizations should be asked where the appropriate measures are relative to these goals in an effort to reach the goals quicker.

8. Clinical Operations Workgroup/Vocabulary Task Force – Recommendations on Governance

Jamie Ferguson, Co-Chair of the HITSC Clinical Operations Workgroup, explained that the Workgroup's Vocabulary Task Force held public hearings on the governance of the value sets and subsets for vocabularies that are required for meaningful use. The Task Force focused on both the particular value sets that are required (e.g., the quality measure value sets that describe the universe of terms or concepts that are required for the numerators and denominators for quality measure reporting), as well as subsets such as the most frequently used codes or the most frequently used terms and concepts in each of the different controlled vocabularies that would be a starter set for implementers as part of their implementation toolkit. The Task Force reported back its early findings at the last HITSC meeting, and now has two recommendations to discuss as a result of those hearings and that previous discussion.

The recommendations are as follows:

- A single federal office or agency should be responsible for ensuring the creation, maintenance, dissemination and accessibility of all vocabulary value sets and subsets related to meaningful use. This entity should coordinate with other federal agencies, SDOs, and relevant stakeholders to:
  - Identify what sets are needed and who will produce and maintain each set
  - Determine the appropriate dissemination schedule and update frequency for each set
  - Establish standard formats for production and dissemination of sets
  - Manage processes for review, testing, approval and publication of sets
  - Ensure the existence of robust, authoritative infrastructure for sets
  - Recommend related education, communications and outreach.

  This entity should ensure federal funding as needed to establish these activities, to support them over time, and to make vocabularies, value sets, and any subsets required for meaningful use available for U.S.-wide use at no cost.

- Establish authoritative infrastructure for the development, maintenance and dissemination of standard value sets and subsets related to meaningful use. "One-stop shopping" for meaningful use vocabularies would:
  - Establish a central repository, central download capability, and central feedback loop mechanism in the federal government for dissemination of meaningful use vocabularies
  - Enable decentralized private or public sector alternative repositories for dissemination that may include alternative distribution mechanisms and schedules, using federally standardized exchange formats
  - Differentiate tight control over specific value sets required for meaningful use, versus loose control to enable sharing other subsets that may be made available for the convenience of EHR implementers and users

– Establish open, public, consensus-based processes to standardize parameters for public and private sector tooling that can make vocabularies searchable and discoverable by EHR end users.

The Vocabulary Task Force discussed the fact that there are different federal offices and agencies with specific legal responsibilities, and that some of the vocabularies that were in the IFR that have been selected for meaningful use have legal requirements in terms of their schedule that are set outside of ONC. In those cases, the Task Force recommends that this central authority should have a coordination function. But, to the extent possible, it recommends that this new or existing federal office would have the ability to control the schedules and the manner of dissemination.

Jamie Ferguson explained that the Task Force is recommending differentiation between tight controls over those things that are required to qualify for meaningful use, versus looser control over the subsets that are more for the convenience of the implementers and the users.

> **Action Item #3:** The Committee accepted the recommendations of the Vocabulary Task Force by consensus and will forward them to the National Coordinator.

Jamie Ferguson then presented two guiding questions to the Committee for discussion:

- The Vocabulary Task Force focused first on vocabulary value sets and subsets required for 2011 meaningful use, including starter sets. Should the scope of these recommendations include the base standards (i.e., the entire vocabularies)?

- The Taskforce's understanding is that ONC authority to establish vocabulary processes and infrastructure is limited to those items directly related to meaningful use regulations, yet stakeholder input suggests that a broader scope for centralized health care vocabulary functions is desirable. Is there a different approach to coordination that may be more effective for EHR implementers and users?

The Task Force believes that it should be within ONC's scope of authority to have control over the dissemination of the value sets that are required in the meaningful use IFR certification regulations. Jamie Ferguson explained that the Task Force limited this to those things that are within the purview of ONC's authority related to the meaningful use regulations. However, they did hear from many stakeholders a desire to have much broader coordination than just those things that are required for meaningful use.

9. Update on NHIN Direct

Arien Malec reminded the group that NHIN Direct is a project with the goal of creating a set of policies, standards, and services. The mission is to enable simple, direct, and scalable transport over the Internet to be used for secure and meaningful exchanges between known participants in support of meaningful use. He suggested that there will be a transition in this country between providers who have simple exchange capabilities to those moving towards more robust exchange capabilities. Therefore, there will be a transition from clinicians using simple modes of transport to the continuity of care that ties back to meaningful use. Some of the transactions that may need to be supported up front may eventually be replaced by more robust HIE transactions.

Doug Fridsma noted that there is potentially a bias in the HITSC workgroups in the sense that there are many larger organizations represented. It will be important to ensure that the NHIN Direct group represents and follows the principles of the Implementation Workgroup (e.g., that it considers smaller organizations). One initiative that will help in this regard is the NHIN Direct wiki, which is open to the public. There currently are 180 members who are actively engaged in dialog. All workgroup meetings and calls are open to the public.

Arien Malec noted that the HITPC NHIN Workgroup's timeline is extraordinarily aggressive, to match the timeline of meaningful use itself. The work is organized around developing real-world implementations involving real-world providers in September or October of this year. He shared their set of delivery objectives and milestones. By mid-June, they would like to have a final set of specifications, and they will report back to this Committee towards the end of June with that final list. This will be the language that people can use to build software.

Their work is also focused on providing a set of testing harnesses, testing tools, and implementation guides that are designed to make it easy to take the specification off the shelf and hook into it. There will also be open source reference implementation so that those on a similar technology stack can simply plug in the reference implementation. Those timeframes are organized around late July.

The final deliverable is the project itself, as a model for how to shepherd new standards through a disciplined process. One of the key deliverables is a set of formalized models for the services and specifications.

In discussion, the following points were made:

- Carol Diamond asked about the policy input needed from the NHIN Workgroup and if there was a workgroup focusing on security and trust-related issues. Doug Fridsma noted that he has suggested that the next NHIN Workgroup meeting include these issues. He acknowledged that the NHIN Workgroup could be doing a better job of coordinating the policy input, and indicated that it is open to working with the full HITPC and HITSC, as well as their Workgroups, in the appropriate areas.

- Dixie Baker noted that there is a disparity in the timelines—the NHIN Direct project is significantly further ahead than the discussions that are currently taking place in the Workgroup.

- In response to a question, Doug Fridsma explained that NHIN Direct is a project that is developing specifications.

10. Drug Enforcement Administration's e-Prescribing for Controlled Substances – Interim Final Rule

Jodi Daniel described how the e-prescribing of controlled substances connects with HHS's HIT efforts as well as its work with the U.S. Drug Enforcement Administration (DEA). The ONC is interested in this issue because it wants to ensure that all providers who want to e-prescribe can do so. The inability to e-prescribe controlled substances has been a significant challenge for those who are interested in e-prescribing and in the broader use of HIT. There are concerns about allowing this in a way that fits with for provider workflow.

The security requirements in the DEA regulations do go further than HHS's health information security requirements. However, they still work well together, and ONC hopes to learn more about how these security policies are implemented and how they work in practice.

Michelle Ferritto, DEA Acting Administrator, explained that the organization has appreciated working with all of the components within HHS on this rule. The interim rule was published on March 31 and becomes effective June 1. A number of question-and-answer documents are available on DEA's Office of Diversion Control Web site—the site includes specifically designed question-and-answer documents for prescribing practitioners, pharmacies, and for application providers about this rule to try to break this lengthy document down into something that is easier to read and applicable for each of the groups involved.

Michelle Ferritto summarized that the rule: (1) provides practitioners with the option of signing and transmitting prescriptions for controlled substances electronically; (2) permits pharmacies to receive, dispense, and archive electronic prescriptions; (3) involves schedule II, III, IV, and V controlled substances; (4) acknowledges that electronic prescriptions for controlled substances are voluntary from DEA's perspective; and (5) still permits written, manually signed, and oral prescriptions for controlled substances, where applicable. She noted that these regulations are also related to any state laws or regulations that may exist, so if a state has laws or regulations that are more stringent than these, those state regulations or laws would need to be complied with as well. Implementation of the rule affects prescribing practitioners, pharmacies, and application providers (which must evaluate the application and reprogram where necessary, as well as undergo third-party audit or certification to determine whether the application meets DEA's requirements). Michelle Ferritto then addressed the specific requirements for each of these groups.

With regard to identity proofing, in the case of individual practitioners, this will be conducted by credential service providers or certification authorities approved by the federal government. Remote identity proofing is permissible. CSP or CA will issue a two-factor credential; institutional practitioners may do this in-house/in person. The application provider will inform the practitioner what CSP or CA to work with. It is hoped that this shift will be seamless, and it is expected that these partnerships will work well. DEA does not anticipate that individual practitioners will have to go searching for entities to conduct their identity proofing for them (application providers will be expected to inform their users on this issue).

Two-factor authentication credentials protect practitioners from the misuse of a credential by insiders, they also protect from external threats because the practitioner can retain control of a biometric or hard token. Two-factor authentication includes two of the following: (1) something one knows (e.g., password, PIN); (2) something one has (e.g., a hard token separate from the computer being accessed); and (3) something one is (e.g., any biometric that meets DEA's requirements). Two-factor credentials will be used only to sign prescriptions and approve access controls.

Michelle Ferritto emphasized that DEA's rule does not require that the credential be used to access the computer as a whole, or the EHR or the e-prescribing application as a whole. The only times that DEA requires it be used is to approve access controls and to sign controlled substance prescriptions.

She explained that access controls are set at the practice by two people, one being a registrant possessing the two-factor credential. Access controls limit the permission to approve and sign controlled substances prescriptions to persons whose: (1) state authorization(s) to practice and to prescribe controlled substances, where applicable, are current and in good standing; (2) DEA registration is current and in good standing. For many practices, setting access controls will not occur frequently. It typically will happen when a system is first initialized to sign controlled substance prescriptions. It will also happen whenever there is staff turnover. In institutions, the concept is the same, but the implementation is different. The DEA envisions it to be implemented by two separate offices within the hospital or clinic. This is to ensure that one person on their own cannot grant someone the authority to sign these prescriptions when that person does not have such authority.

Michelle Ferritto then described how controlled substance prescriptions are signed. First, a practitioner or agent may prepare the prescription for review and signature by the practitioner. The practitioner then accesses the list of prescriptions for a single patient. Onscreen, the following are displayed: (1) date of issuance; (2) patient name; (3) drug name, strength, form, quantity prescribed, directions for use; (4) name, address, and DEA registration number of the practitioner; and (5) other information as applicable. On that same screen is a statement indicating that completion of the two-factor authentication protocol equates to legally signing the prescription(s) and authorizes transmission to the pharmacy for the dispensing displayed. Then, the practitioner indicates those prescriptions ready to be signed and is prompted to complete the two-factor authentication protocol. Authentication causes the application to digitally sign DEA elements and archives or causes the practitioner's digital certificate to digitally sign DEA elements and archive. Information not required by DEA may be added after signature (e.g., pharmacy URL).

Several issues relate to the transmission of the prescription. For example, transmission should be as soon as possible after signature, but need not be immediate. The prescription must remain electronic; conversion to fax is not permitted during transmission. In addition, the prescription may be printed after signature if labeled "copy only - not valid for dispensing." Information may be transferred to electronic medical records; lists of prescriptions may be printed if they are indicated as not for dispensing. A transmitted prescription may be printed for manual signature if the practitioner is notified that the transmission failed; the practitioner must indicate that the original was electronic and include the name of the pharmacy as well as the date/time transmitted. Michelle Ferritto emphasized that all electronic prescriptions for controlled substances, once transmitted, must remain electronic throughout. They cannot be converted to facsimile during transmission.

Pharmacies will set access controls to ensure that only authorized persons can annotate, alter (where permissible), or delete prescriptions. The pharmacies receive and archive prescriptions—all annotations and records must be electronic.

DEA recognizes that there is the potential for security incidents within this system, and so it requires that electronic prescription or health record applications that are conducting e-prescribing activities and pharmacy applications must conduct internal audits on a daily basis to determine whether a security incident has occurred. Those audits examine a number of different elements in an automated fashion. The audit review generates a report for human review.

These rules also affect applications. For example, they must allow access controls, require the use of two-factor credential for signing, have an audit trail, digitally sign and archive records, and include all DEA-required information in the prescription record. In addition, the applications must be able to import, display, and store DEA information in the record and generate a record of controlled substance prescriptions for review.

The DEA recognizes that it would be very difficult for an individual practitioner or a pharmacy to know on their own, independently, whether an application meets the requirements. The DEA requires that application providers undergo third-party audits of their application.

The ensuing Committee discussion included these points:

- John Halamka asked if a cell phone would be considered as a hard token. He argued that it is a hardware device, which one could uniquely register through one of the organizations that would do the of identity proofing. Clinician acceptance of carrying cell phones is very high; clinician acceptance of carrying a secure ID type token is very low. Michelle Ferritto indicated that a cell phone could serve as a hard token—it would depend on whether the application on the cell phone met the requirements that DEA has included for a hard token. Those have to do with several different federal information processing standard requirements.

- From the DEA's perspective, there are no requirements pertaining to the network that exchanges the information between the pharmacy and the e-prescribing application.

- John Derr asked whether DEA would consider the nurse as an agent, because in nursing homes there is a three-way communication among the prescriber, the pharmacy, and the nursing facility. Historically, the DEA has not recognized the nurse as a prescriber or as an agent. Michelle Ferritto re-emphasized the requirements of existing regulations for DEA that are addressed in this rule, which state that prescriptions for controlled substances must be signed by DEA-registered practitioners.

- Michelle Ferritto noted that several auditors have already been identified. The DEA would look at how prospective auditing entities plan to conduct their certifications. Once a particular entity is approved, DEA would publish an entry in the *Federal Register* indicating that the company has been approved to conduct, as a certification organization, electronic prescriptions for controlled substances or pharmacy applications. This information would be posted on the DEA Web Site as well.

- Kevin Hutchinson asked why a prescription, after being properly authenticated, could not then be delivered by fax in the event of a loss of connectivity. Michelle Ferritto clarified that it is legal to fax written and manually signed prescriptions for Schedule III, IV, and V controlled substances. Electronic prescriptions will not provide that same type of manual, physical signature for the pharmacy to know that they have been signed by the DEA registrant. Instead, there are other electronic means that the rules envision for that pharmacy to know that the prescription has been signed in a manner that meets DEA's requirements. To turn that into an unsigned facsimile invalidates the prescription. Kevin Hutchinson commented that this implies that a two-factor digital sign is not a stringent signature. Michelle Ferritto disagreed, noting

that there are distinct requirements for electronic prescriptions, and distinct requirements for paper prescriptions. Kevin Hutchinson said he believes that is going to be disruptive to the process, because connectivity issues are going to happen.

- Jodi Daniel noted that this is an interim final rule, and the comment period is still open.

11. Public Comment

- Bill Briefwaite, retired physician and CMO of Anicam, applauded the DEA and ONC for the publication of this rule. He commented that the DEA seems to have judged the use of out-of-band tokens as not acceptable only because the DEA "doubts" that they are practical because they require more time for each authentication. He suggested that this is not a security issue, and that DEA should let the market decide whether that sort of technology can be timely or not. Unless there is some unspoken security flaw in the use of out-of-band tokens, and when they are used appropriately, he indicated that DEA should clarify in a technical correction before the June 1 date so that organizations do not worry about this and move to other technologies. He suggested that DEA adopt the National Institute of Standards and Technology definition of out-of-band tokens, and make it clear that those are acceptable alternatives.

- Peter Kaufman, CMO of DrFirst, commented that the reason one could not use a Blackberry as a sole device is that the rule clearly states that the hard token needs to be on a separate device from the computer. The Blackberry could potentially be the hard token, but then the practitioner would have to be e-prescribing on another device. Secondly, the physicians in a trial of theirs in Western Massachusetts who are using hard tokens all expressed concerns about the hard tokens before the study, but now that they are actually prescribing with the hard tokens, and they do not find it to be an issue at all. None of them have had complaints about the hard token in actual use, and there are 79 users up and running. He asked about sending prescriptions while waiting for National Council for Prescription Drug Programs to go through the process that will take almost 2 years to generate a DUF, get the DUF approved, and have that version of script approved by CMS to include a field in which to send a flag indicating that the prescription was signed electronically. He asked whether DEA was working on a temporary solution—without one, it may not be possible to use this system starting on June 1, 2010.

- Brian Ahier, Health IT Evangelist for Mid-Columbia Medical Center, asked a question regarding the definition of meaningful use and the percentage of eligible or permissible prescriptions that will be required to e-prescribe when this rule becomes final. He noted that although many providers are going to be very happy with the ability to e-prescribe controlled drugs, if one is already on their way down the path towards meaningful use and is currently e-prescribing, that provider may not be quite ready for the dual-factor authentication to e-prescribe narcotics. This may increase the percentage of drugs that are not currently being e-prescribed.

- American Society of Consultant Pharmacists President Shelly Spiro asked if a physician who uses a long-term care facility EHR with electronic prescribing incorporated into it, whether or not that facility is not a registrant themselves, can actually enter the electronic prescription into that facility's EHR and then transmit it to the pharmacy. She also asked whether that long-

term care facility can act as an intermediary and be the entity that transmits the prescription directly to the pharmacy.

- Richard Singerman of The Singerman Group referred to a comment that was made about the horizon scan that was discussed for e-measures. The comment was that there is a desire to examine e-measures from top-performing organizations, both those measures that require workflow reengineering and those that do not. He suggested that there is a significant opportunity broaden that scan, so that if organizations are seeing progress along certain e-measures, it would be helpful to have the context in which that progress was made. One could see where the improvements were made and examine whether the organization is a staff model, a closed system like Kaiser and the Veterans Administration, or a mixture of a staff model and external physicians or non-staff. Through this approach, once could look at the entire value chain from a certain improvement that was made according to an e-measure, in its proper context or environment. That would tie into some of the Implementation Workgroup's concerns about not using a one-size-fits-all solution for adoption.

SUMMARY OF ACTION ITEMS

Action Item #1: Minutes from the last HITSC meeting, held on March 24, 2010, were approved by consensus with one correction: on page 7, the reference to "*government* of standards-development organizations…" should read as "*governance* of standards development organizations..."

Action Item #2: Committee members agreed by consensus to provide additional input to David Blumenthal, Doug Fridsma, and the ONC on: (1) the activities and spectrum of interoperability framework and recommendations on cross-links necessary for the appropriate structure to support, (2) the recommendations that arose in terms of the pragmatism and representation, and (3) linkages between the HIT Policy and HIT Standards Committees.

Action Item #3: The Committee accepted the recommendations of the Vocabulary Task Force by consensus and will forward them to the National Coordinator.